4.30: COVID in Children and the US FDA Vaccine Advisory Committee with Dr. Cody Meissner

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We Discuss:

- Introduction [1:00]
- Authorizations for minors [4:35]
- Viruses previously acquired [11:00]
- Education [20:00]
- Masks [35:48]
- Boosters [37:34]
- Boosters continued [57:02]

Plenary Session 4.30 Show Notes

Overview

Conversation with Dr. Cody Meissner

- YouTube
 - Watch this conversation on YouTube
- Introduction [1:00]

- Dr. Cody Meissner
 - Dr. Meissner is the Chief of the Division of Pediatric Infectious Disease and a Professor of Pediatrics at Tufts University School of Medicine
- Vaccine outlook
 - Dr. Meissner recognizes the absolute importance of the vaccines
 - He points out that the current rate of vaccine preventable diseases in the United States is lower than ever before in our history
 - This is because the uptake of these vaccines is higher than ever before
 - We know that COVID-19 vaccinations are safe and effective in adults, but we don't know what they are like in children currently

• Authorizations for minors [4:35]

- Presentation of modeling done by the US FDA
 - Model Parameters:
 - 1. What might we expect in terms of SARS-CoV-2 infections in the next 120 days?
 - Using the assumption kids 5 to 11 will have the same rate of myocarditis as kids 12 to 15, we can leverage <u>Optum</u> as the insurance dataset for that estimate
 - 3. What is the risk that 5-11 y/o's will be hospitalized if they were to acquire the virus?

"All of the parameters did not leverage the pivotal trial data, the randomized controlled trial, all of the estimates that they use in the model are from other data sources that pre-existed or existed separately from the pivotal trial to the 4700 person randomized control trial" - VP

• Mathematical models

- Overall, models are important
 - They allow us to predict what will happen next, but keep in mind that the history of mathematical models for COVID-19 has been inaccurate in many instances.
 - A mathematical model is only as good as the base case assumptions

"I certainly don't mean to criticize any of the mathematical models. I'm only pointing out how difficult it is to conduct and conclude exactly what's going to happen next." - Dr. Meissner

• Viruses previously acquired [11:00]

- One of the fundamental ideas of vaccinology is that you cannot vaccinate someone who will not benefit from the vaccination
 - The benefit of COVID-19 vaccination for children is not clear
 - If there is little to no benefit, then we will be subjecting children to mandatory vaccination to protect the 60 million or so people who are so obstinate that they won't receive the vaccination
 - We would then be exposing children to potential hazards unnecessarily
 - Hazard e.g., → myocarditis
 - The risk of hospitalization due to myocarditis in a young male following the second dose of a messenger RNA vaccine is several times greater than the risk of COVID hospitalization in the same cohort
- Should we be screening for children for zero prevalence before vaccination?
- Education [20:00]
 - In regard to vaccine mandates, there is a current disparity in vaccination rates
 - Example

 How lagging vaccination rates could keep the Bay Area's Black students out of

<u>school</u>

Vaccination rates for Bay Area teens

Click on the labels to see the percentage of children 12-17 years old in the 5-county Bay Area who have received at least one dose of a COVID vaccine.



**Data for Pacific Islanders and Native American teenagers only provided by Alameda and San Mateo counties. By: Harriet Blair Rowan - Bay Area News Group

• Masks [35:48]

- There are still many open questions in regard to masking
 - Particularly, the real question for children is "what is the harm that comes from wearing a mask every day in school?"
 - Maybe the benefit outweighs the harm, and before we take such a dramatic step, we should be able to answer this question via randomized trials
- Boosters [37:34]
 - Dr. Marion Gruber and Dr. Philip Krause

- <u>Two Top F.D.A. Vaccine Regulators Are Set to Depart During a Crucial</u> <u>Period</u>
 - NYT article
- Questions regarding boosters and outcomes

"What I really care about in boosters, whether it's the third booster or the fourth booster [the fifth booster] is: Do you reduce hospitalizations, bad outcome, severe COVID versus not getting the booster?" - VP

- Will a booster dose prevent those asymptomatic or mild upper respiratory tract infections?
 - There are certainly people in high risk categories (e.g., immunodeficient) that we want to do as much as we can to protect
 - But if you're an otherwise healthy individual, the likelihood are of acquiring severe disease after two doses of either the messenger RNA vaccines or Johnson & Johnson is low
- The key issue is, when there is a pending approval, policy change, or EUA → we need really large randomized control trials for all these questions
 - We need trials powered for harm, and the harms that must be focused on are the number of hospitalizations and fatalities
- Boosters continued [57:02]
 - Safety signals
 - There's lots of barriers in practice to reporting in a passive surveillance system

"I do hope that after all this, we think about maybe even more active collection of safety information for products that are debuted on" - VP

<u>V-safe After Vaccination Health Checker | CDC</u>

• Dr. Meissner points out that the FDA has and the CDC have done a strong effort to try and confirm the rates of safety signals

Plenary Session is a podcast on medicine, oncology, & health policy.

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